Addressing COVID-19 Vaccine Hesitancy in Rural Community Pharmacies Reducing Disparities Through an Implementation Science Approach

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PROTOCOL

Complete Title: Addressing COVID-19 Vaccine Hesitancy in Rural Community Pharmacies Reducing Disparities Through an Implementation Science Approach

Short Title: COVID-19 Vaccine Hesitancy Counseling Intervention for Pharmacists

Sponsor: National Institutes of Health (NIH)

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Version Date: March 19, 2025

I confirm that I have read this protocol and understand it.

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Date: 3/19/25

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Abbreviations and Definitions of Terms

Abbreviation	Definition
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
HPV	Human papillomavirus
CFIR	Consolidated Framework for Implementation Research
RURAL-CP	Rural Research Alliance of Community Pharmacies
VA	U.S. Department of Veterans Affairs
QUERI	Quality Enhancement Research Initiative
LMM	Linear Mixed-effects Model
GLMM	Generalized Linear Mixed Model
ICC	Intraclass Correlation Coefficients
SP	Standardized Patient

Study Title	Addressing COVID-19 Vaccine Hesitancy in Rural Community Pharmacies Reducing Disparities Through an Implementation Science Approach
Funder	National Institutes of Health (NIH)
Study Rationale	• The COVID-19 pandemic has disproportionally impacted rural communities. • When compared to urban populations, individuals living in rural areas are more vaccine hesitant, have a higher prevalence of comorbid health conditions, and are at greater risk from SARS-CoV-2 variants. Thus, interventions to increase vaccine uptake in rural areas are greatly needed. • Community pharmacists are well-positioned to address vaccine hesitancy with underserved, rural populations. • Because vaccination conversations are sensitive and often politically charged, pharmacists need implementation support, including training and ongoing guidance to deliver evidence-based vaccine hesitancy counseling interventions • Implementation facilitation, in which trained facilitators coach and troubleshoot problems with professionals as they implement new practices, increases adoption of practices with fidelity. • Facilitation generally, and virtual facilitation (e.g., video coaching) in particular, has not been systematically studied in community pharmacy settings.
Study Objective(s)	**Primary** • To evaluate whether virtual facilitation improves fidelity to the vaccine hesitancy counseling intervention when compared to standard implementation. **Secondary** • To evaluate whether virtual facilitation increases intervention effectiveness, defined as a higher number of vaccine hesitant individuals who receive the vaccine, when compared to standard implementation.
Test Article	We have refined an evidence-based vaccine hesitancy counseling intervention with extensive feedback from rural pharmacists, resulting in a 5-step counseling process (ASORT): • **A**sk if they would like to receive a COVID vaccination • **S**olicit their main vaccine concern • **O**ffer to address their concerns • **R**ecommend the vaccine • **T**ry again later if they refuse or are unsure
Study Design	This is an implementation science study. We will use a randomized clinical trial with an adapted stepped-wedge design and 30 rural

	pharmacies. Mixed methods will provide triangulation, expansion, and explanation of quantitative findings.
Subject Population key criteria for Inclusion and Exclusion:	Data will be collected from rural pharmacies located in 7 southeastern states that participate in the Rural Research Alliance of Community Pharmacies (RURAL-CP). **Inclusion Criteria** 1. be a member of RURAL-CP 2. be located in a county that has an African American population of at least 25% or had at least 51% of the population vote for a Republican president in 2020. 3. stock the Covid-19 vaccine for the duration of the study Each pharmacy will contribute at least 1 pharmacist and up to 4 additional pharmacy staff members for the study. Pharmacy staff will be eligible if: • they are at least 18 years of age • they can read and speak English • they have been employed by the pharmacy for at least 1 month **Exclusion Criteria** • There are no exclusion criteria for pharmacy staff
Number Of Subjects	30 pharmacies and up to 150 subjects
Study Duration	Pharmacies will participate in the study for 6-12 months. Total anticipated study duration will be 2 years.
Study Phases	1. Screening: identifying pharmacies in the RURAL-CP network that meet the eligibility criteria 2. Enrollment by invitation: inviting select pharmacies via email, confirming eligibility of those interested, obtaining verbal informed consent 3. Standard Implementation Period: participants complete one or two 8-week period(s), which involves: completing a 30-minute online training; watching a webinar; implementing the vaccine hesitancy counseling intervention with 10 vaccine hesitant patients per 8-week period; meeting with an SP once per month to have their fidelity to the intervention evaluated 4. Virtual Facilitation Period: participants complete one or two 8-week period(s), which involves: a virtual site visit from a trained virtual facilitator; at least weekly calls with the facilitator; implementing the vaccine hesitancy counseling intervention with 10 vaccine hesitant patients per 8-week period; meeting with an SP once per month to have their fidelity to the intervention evaluated 5. Follow-up: select pharmacies will have one 8-week follow-up period, during which they will continue to implement the vaccine hesitancy counseling intervention with 10 vaccine hesitant patients 6. Qualitative Data Collection: select participants (12 total) will complete a 60-minute interview to assess feasibility and performance of the implementation approaches

Efficacy Evaluations	Primary outcome: trained study staff will use a fidelity observation guide to rate pharmacists' vaccine hesitancy counseling during recorded counseling sessions. The fidelity measure focuses on the competence of the pharmacist (7 items) in their delivery of the vaccine hesitancy counseling intervention. Each competence item will be assessed on a scale from 0 to 2, with 0 = skill not demonstrated, 1 = skill needs development, and 2 = skill demonstrated with competence. Secondary outcome: using an online survey, pharmacists will document the following on a daily basis: A) how many vaccine-hesitant individuals they provided vaccine hesitancy counseling to; B) of those individuals, how many received a COVID-19 vaccine; C) the self-reported age, race, and gender of the individual who was counseled. Effectiveness will be calculated as the proportion of counseled individuals who received a vaccine, or B/A. Scores will range from 0 to 1.
Statistical And Analytic Plan	For the primary analysis of the fidelity outcome, linear mixed-effects models (LMM) will be used to compare the level of fidelity between the two implementation approaches (standard vs. virtual facilitation). We will report point estimates for the group mean difference along with a 95% confidence interval. Generalized linear mixed models (GLMM) will be used for analysis of the secondary outcome of effectiveness.
DATA AND SAFETY MONITORING PLAN	The study PIs will review interview and survey data as well as fidelity data on a quarterly basis for safety issues. In addition, the entire study team will meet monthly to discuss the study's progression and any potential safety or data concerns.

BACKGROUND AND RATIONALE

Major health crises like the COVID-19 pandemic have disproportionally impacted rural communities, which are frequently health professional shortage areas that lack health care infrastructure, including hospitals[1-3]. As one of the most accessible health professionals in rural areas[4,5], community pharmacists are a notable exception to this lack of infrastructure. There are =68,000 community pharmacies in the U.S, many of which have convenient hours and offer free walk-in services[6].

When compared to urban populations, individuals living in rural areas are more vaccine hesitant [8,9] and have a higher prevalence of health conditions that increase their risk for severe COVID-19 illness and death[12]. Higher vaccine hesitancy is strongly correlated with lower vaccination rates[13], with rural counties driving lower state-level vaccination rates in the South[14,15], which has some of the lowest vaccination rates in the country. Unless vaccine hesitancy is addressed, low vaccination rates and a lack of vaccine mandates mean these communities remain susceptible to SARS-CoV-2 variants. Pharmacists, one of the most trusted sources of medication information [16], can serve as strong allies to address vaccine hesitancy. Rural patients see their community pharmacist ~14 times per year; nearly three times more than they see a primary care provider[17]. Thus, pharmacists can address vaccine concerns on a monthly basis and make repeated vaccination offers.

To engage in sensitive vaccine conversations that pharmacists have referred to as "charged", they need updated information to address patients' evolving vaccine concerns and implementation support, including training and ongoing guidance, to deliver evidence-based vaccine hesitancy counseling interventions[18]. A *standard implementation approach,* which typically involves training and dissemination of implementation support tools (e.g., sample workflows, counseling "cheat sheets"), is commonly used to help health professionals implement new practices, including HPV vaccination[19]. Although necessary, this standard approach is usually not sufficient to promote adoption of a new and complex practice with fidelity [20-22]. In recognition of this limitation, a growing body of research shows that *implementation facilitation* can increase implementation fidelity[23-26] by having trained facilitators build trusting relationships with health professionals to monitor their implementation progress, provide feedback, and reinforce change. To date, implementation facilitation has not been systematically studied in community pharmacy settings. Moreover, little is known about the effectiveness of *a virtual facilitation approach*, whereby facilitators connect with health professionals *exclusively* via telephone and video. The need to study virtual facilitation is highly relevant given that travel to remote rural locations is resource-intensive and has been restricted due to pandemic-related safety concerns.

1 STUDY OBJECTIVES

The overall objective is to test the effects of a *standard implementation* approach and the addition of *virtual facilitation* on rural pharmacists' ability to implement COVID-19 vaccine hesitancy counseling, using an incomplete stepped wedge design[27]. Data will be collected on the primary trial outcome of counseling fidelity (competence) and the secondary outcome of intervention effectiveness (vaccination rates). Pharmacies will implement the ASORT intervention, which was adapted from an evidence-based vaccine hesitancy intervention[28] with extensive qualitative input from rural pharmacists[29]. The intervention will be updated frequently to address new vaccine concerns as they arise.

We have two specific aims.

1.1 Aim 1

Compared to the standard implementation approach, test whether adding virtual facilitation increases (a) the fidelity with which pharmacists implement the vaccine hesitancy counseling intervention and (b) the number of vaccine hesitant patients who receive the vaccine. Our primary outcome is pharmacist fidelity to the vaccine hesitancy counseling intervention and our secondary outcome is intervention effectiveness (i.e., the number of vaccine hesitant individuals who receive a vaccine). We hypothesize that:

H_1: Virtual facilitation will improve fidelity to the vaccine hesitancy counseling intervention when compared to standard implementation.

H_2: Virtual facilitation will increase intervention effectiveness, defined as a higher number of vaccine hesitant individuals who receive the vaccine, when compared to standard implementation.

1.2 Aim 2

Conduct a cost assessment and explore potential sustainability of the implementation approaches. We will conduct a time-driven, activity-based cost analysis and a budget analysis of the standard implementation and virtual facilitation approaches. Additionally, a payer advisory board will review these data and advise on how to make virtual facilitation sustainable through reimbursement models. We do not have a hypothesis associated with this aim.

2 INVESTIGATIONAL PLAN

2.1 Study Design

This is an implementation science study. We will use a randomized clinical trial with an adapted stepped-wedge design and 30 rural pharmacies to determine the effectiveness and incremental cost-effectiveness of a standard implementation approach compared to the addition of virtual facilitation by a trained facilitator in support of the delivery of a COVID-19 vaccine hesitancy counseling intervention. Mixed methods will provide triangulation, expansion, and explanation of quantitative findings.

In the incomplete stepped wedge cluster randomized design, each pharmacy will begin in the standard implementation approach condition for one or two 8-week periods and then "crossover" to the virtual facilitation condition for one or two 8-week periods. Length of time in each condition depends on the "step" to which pharmacies are randomly assigned. Figure 1 depicts the "stairstep" study design and

pharmacy assignment. For blocks 1–4, we will continue to collect data during one 8-week follow-up period to evaluate the potential impact of the virtual facilitation approach on sustained intervention fidelity and effectiveness once virtual facilitation has been stopped.

2.2 Allocation to Treatment Groups

In this stepped-wedge trial, pharmacies will be randomized in blocks at the time they begin the initial intervention condition (standard implementation). We will create 6 blocks of pharmacies, with 5 pharmacies randomized to each block by the trial statistician. To ensure balance, the block randomization will be stratified by two measures of pharmacy size—the number of patients and number of pharmacists.

2.3 Number of Subjects and Study Duration

The stepped-wedge trial includes 30 pharmacies and up to 150 subjects. Subjects will include 30 pharmacists (1 from each pharmacy) and up to 120 pharmacy staff (up to 4 staff from each pharmacy), such as pharmacy technicians and cashiers. Pharmacies will participate in the study for 6-12 months, depending on the block to which they are randomly assigned. Total anticipated study duration will be 2 years, with 15 pharmacies participating in year 1 and 15 participating in year 2. The study follows the distribution of COVID-19 vaccines in the USA, which follows the Northern Hemisphere's "flu season"—approximately August-February each year. We expect that the first COVID-19 vaccination season in the fall of 2023 will be delayed due to vaccine availability and will begin in October and run through March 2024. In 2024, we expect that availability issues will not occur and the vaccine will be available during the standard flu season from August-February. All pharmacies begin the study in the fall. Block 1 and blocks 4-6 will participate for 6 months (Oct-Mar and Aug-Jan, respectively). Blocks 2 and 3 begin in Oct 2023 and participate for 6 months alongside Block 1, but then have an 8-week follow-up period Aug-Sep 2024 (Figure 1).

2.4 Study Population

All data will be collected from rural pharmacies that participate in the Rural Research Alliance of Community Pharmacies (RURAL-CP), which was established by this trial's multiple principal investigators Carpenter and Curran in 2020. RURAL-CP is the first practice-based research network for rural community pharmacies and aims to reduce rural health disparities by supporting high-quality implementation research with community pharmacies. Thirty pharmacies will be recruited from a total of 127 RURAL-CP pharmacies located in seven states throughout the Southeast. For a pharmacy to be eligible for the trial, it must: be a member of RURAL-CP; be located in a county that has an African American population of at least 25% or had at least 51% of the population vote for a Republican president in 2020. The reason for this criterion is that these populations are more vaccine hesitant; and stock the Covid-19 vaccine for the duration of the study. Each pharmacy will contribute at least 1 pharmacist and up to 4 additional pharmacy staff members for the study, including pharmacy technicians and cashiers. Pharmacy staff will be eligible if: they are at least 18 years of age; they can read and speak English; and they have been employed by the pharmacy for at least 1 month. There are no exclusion criteria for pharmacy staff.

3 STUDY PROCEDURES

3.1 Recruitment

Study staff have identified pharmacies in the RURAL-CP network that meet the eligibility criteria. The program manager for RURAL-CP will inform all eligible member pharmacies about the proposed study via email and ask interested pharmacies to respond stating their interest. Subsequent discussions will explain the purpose of the study and study procedures. Pharmacies interested in participating will identify potential pharmacy staff respondents and provide their contact information to the PIs. These potential respondents will be contacted by study staff to ask them if they would like to participate in the study. A consent script will be created by the research team for recruitment that will include a description of the study and what will be expected of participants. Verbal consent will be obtained from all subjects.

3.2 Standard Implementation Period

After pharmacy participants are enrolled, they will then complete one or two 8-week "standard implementation" period(s), depending on the step to which they are randomly assigned. At the beginning of this period, they will be asked to complete a 30-minute online training about COVID-19 vaccine hesitancy counseling and watch a live or pre-recorded webinar (their choice) that provides up-to-date information about COVID-19 vaccinations and boosters. After completion of the training and webinar, participants will be asked to implement the vaccine hesitancy counseling intervention with 10 vaccine hesitant patients per 8-week period. Pharmacists will use Qualtrics or a paper survey to document the extent to which the intervention results in customers getting vaccinated. They will specifically document the number of customers they offered the intervention to, the number who refused, and the number who agreed to be vaccinated. No identifiable customer-level data will be provided by the pharmacies.

Additionally, during the standard implementation period(s), trained study staff will observe and rate counseling fidelity two times per month for each participating pharmacy. We will use a fidelity rating scale to assess fidelity of delivery of the intervention during 4-8 total observed intervention sessions per pharmacy (4 per 8-week period). Since pharmacists have reported difficulties getting patients to agree to be recorded, affecting data collection, we will use standardized patients (SPs) in lieu of real patient conversations. Two SPs will have a total of 8 standardized scripts, each expressing different concerns about the Covid vaccine. The project manager will schedule a 20-minute block with an SP and participating pharmacist and send a Zoom link. Pharmacists will be randomized to script and order of the presentation of two SP scenarios. On the Zoom call, SPs will enact two of their cases, to which the pharmacist will ideally respond with the ASORT intervention. The encounter will be recorded using the secure Express Dictate mobile or desktop app and later rated for counseling fidelity. SPs will meet with each pharmacist one time per month, portraying different personas each time.

To increase the likelihood that each participating pharmacy submits the requested study data, a fax will be sent to each participating pharmacy that is missing data after the first month of standard implementation to remind them of what is needed. This fax may be sent every 2 weeks as needed to acquire missing study data, with a follow-up phone call a week after the fax to non-responders.

At the end of the standard implementation period(s), participating pharmacy staff (up to 5 per pharmacy) will complete Qualtrics surveys to assess implementation outcomes (feasibility, acceptability, appropriateness).

3.3 Virtual Facilitation Period

After the implementation outcome surveys have been completed, pharmacies will "crossover" to the virtual facilitation period(s). This period will begin with a virtual site visit from a trained virtual facilitator and be followed by at least weekly calls with a local champion (a participating pharmacist) and at least bi-weekly calls with each participating pharmacist to provide feedback on intervention fidelity (from observations of interventions delivered). The virtual site visit over Zoom will establish the personnel and workflows at each pharmacy and allow the facilitator to establish rapport. Weekly Zoom calls will allow the virtual facilitator to work with a site champion to review overall implementation challenges associated with approaching patients, delivering the intervention, and documenting results. Lastly, either the facilitator or the local champion can request and schedule a Zoom call to go over any pressing implementation issue in need of rapid attention (e.g., technical difficulties with the website).

During each 8-week virtual facilitation period (one or two periods, depending on the step to which pharmacies are randomly assigned), pharmacists will again be asked to implement the intervention with 10 vaccine hesitant patients. Like during the standard implementation period, pharmacists will use Qualtrics or a paper survey to document the extent to which the intervention results in customers getting vaccinated. Similarly, fidelity observations (4-8 total per pharmacy) will be collected using the same processes described in Section 3.2. Additionally, at the end of virtual facilitation period(s) participating pharmacy staff (up to 5 per pharmacy) will again be asked to complete Qualtrics surveys to assess implementation outcomes (feasibility, acceptability, appropriateness).

3.4 Follow-up

Pharmacies randomized to blocks 1-4 will have one 8-week follow-up period. During this period, pharmacists will continue to use Qualtrics or a paper survey to document the extent to which the intervention results in customers getting vaccinated. They will specifically document the number of customers they offered the intervention to, the number who refused, and the number who agreed to be vaccinated.

3.5 Qualitative Data Collection

After pharmacies complete both the standard and virtual facilitation periods, study staff will conduct qualitative interviews with the primary study participant from one high performing and one low performing pharmacy in each block (12 pharmacies total) to assess feasibility and performance of the implementation approaches. It will also assess: 1) associations observed for organizational structure and culture/climate measures associated with fidelity and effectiveness, 2) sustainability potential, and 3) costs at the pharmacy level. Each interview is expected to last 60 minutes.

4 STUDY EVALUATIONS AND MEASUREMENTS

4.1 Primary Outcome

Our primary outcome is fidelity to the vaccine hesitancy counseling intervention, assessed at the pharmacy level. Our fidelity measure is based on a theoretical framework of fidelity measurement[30] as well as a validated fidelity checklist[31]. The fidelity measure focuses on the competence of the pharmacist (7 items) in their delivery of the vaccine hesitancy counseling intervention.

The competence items focus on the skillfulness of intervention delivery: expressed empathy; used a non-confrontational manner; spoke confidently without using jargon; emphasized patient autonomy; reflected back patient's statements accurately; used a respectful demeanor, and used evidence-based responses when responding to patient vaccine concerns. Each competence item will be assessed on a scale from 0 to 2, with 0 = skill not demonstrated, 1 = skill needs development, and 2 = skill demonstrated with competence. Competence scale scores will range from 0 to 14, with higher scores reflecting greater competency in the delivery of ASORT. Fidelity will be measured for each pharmacist approximately twice per month under the standard implementation approach and approximately twice per month under the virtual facilitation approach. In pharmacies with more than one pharmacist, fidelity ratings will be averaged to achieve a pharmacy-level measure.

Trained staff will rate fidelity after reaching 80% inter-rater reliability during training[32]. Staff who are blinded to the pharmacist's group assignment will use a fidelity observation guide to rate pharmacists' vaccine hesitancy counseling during recorded counseling sessions. During virtual facilitation, ratings will be shared with the facilitators who provide feedback and coaching to pharmacists towards improving fidelity.

4.2 Secondary Outcome

The secondary outcome of effectiveness will be assessed on a monthly basis. Pharmacists will be instructed to deliver vaccine hesitancy counseling to one to two vaccine-hesitant individuals each week (towards a target of at least 5 per month). Using Qualtrics or a paper survey, pharmacists will document the following on a daily basis: A) how many vaccine-hesitant individuals they provided vaccine hesitancy counseling to; B) of those individuals, how many received a COVID-19 vaccine; C) the self-reported age, race, and gender of the individual who was counseled.

Effectiveness will be calculated as the proportion of counseled individuals who received a vaccine, or B/A. Individuals who are counseled and schedule a vaccine at a later date will not be counted in the numerator (B) until they have actually received a vaccine. Effectiveness scores will range from 0 to 1, with higher scores reflecting a greater percentage of vaccine-hesitant individuals who received a vaccine. During virtual facilitation, trial facilitators will be provided with bi-weekly effectiveness data so they can share the results with the pharmacies to assess performance and identify ways to improve implementation processes and intervention effectiveness.

4.3 Other Measures

Acceptability, appropriateness, and feasibility of the vaccine hesitancy intervention and implementation approaches (standard, facilitation) will be measured using validated surveys[33]. Each

measure includes 4 items (e.g., “intervention X seems doable” [feasibility]) measured on a 5-point response scale that ranges from “strongly disagree” (coded as 1) to “strongly agree” (coded as 5). For each pharmacy, we will average scores across the pharmacy staff members who complete the surveys.

Uptake will be calculated as the number of times vaccine hesitancy counseling was offered divided by the number of individuals who expressed vaccine hesitancy when offered the vaccine.

Sustainment will be assessed by the continued measurement of fidelity, effectiveness, and uptake during the “follow-up” periods.

Organizational structure and context measures[34]: one pharmacist per pharmacy will complete the Organizational Structure survey[35,36], which measures: location, type (e.g., independent, chain), setting (e.g., retail, specialty), size (weekly prescriptions, staffing), technological capacity (dispensing system), and services provided. The Organizational Context measure (completed by 5 pharmacy staff members) assesses CFIR inner setting constructs[34] that reflect organizational culture/capacity for change[37], learning climate, leadership, and resources[38,39]. All items are measured on a 5-point agree-disagree response scale, with higher scores reflecting a stronger implementation context. For each pharmacy, we will average scores across the five pharmacy staff members who complete the surveys.

5 STATISTICAL CONSIDERATIONS

We will use the principles of intention-to-treat, using multiple imputations if needed for missingness, for all statistical analyses related to primary and secondary endpoints. Descriptive statistics will be computed for all quantitative implementation outcomes in Table 1.

5.1 Primary Outcome

The primary outcome of fidelity is captured at the pharmacy level. For our primary analysis of the fidelity outcome, we will use linear mixed-effects models (LMM) to compare the level of fidelity between the two implementation approaches (standard approach vs. virtual facilitation). We will report point estimates for the group mean difference along with a 95% confidence interval. The model-building approach will follow four analyses steps: 1) an unadjusted before/after of the effect of the virtual facilitation approach (ignoring period/time effect); 2) the time period (i.e., steps/blocks) to examine if any potential intervention effect relates only to the intervention or also to an independent effect of calendar time; 3) an adjustment for potential pharmacy-level confounders, such as size and learning climate; and 4) the interaction between period and intervention effect.

5.2 Secondary Outcome

For the secondary outcome of effectiveness, we will use generalized linear mixed models (GLMM) to investigate whether pharmacies are more effective at addressing vaccine hesitancy during virtual facilitation when compared to standard implementation. The effectiveness outcome will be binary (vaccine-hesitant patient accepts vaccine after counseling = 1; vaccine-hesitant patient does not accept vaccine after counseling = 0). We will report the odds ratio estimate of accepting the vaccine after counseling for the virtual facilitation approach (facilitation versus standard) along with a 95%

confidence interval. The model-building approach for our secondary effectiveness outcome will follow four analysis steps: 1) an unadjusted before/after of the effect of the virtual facilitation approach (ignoring period/time effect); 2) the inclusion of time period (i.e., steps) to examine if any potential intervention effect relates only to the intervention or also to an independent effect of calendar time; 3) an adjustment for patient's age, race, and gender and potential pharmacy-level confounders, such as pharmacy size; 4) the possible interaction between time period and intervention. The impact of virtual facilitation on effectiveness could potentially change over time if vaccine acceptance rates increase with time and as pharmacists gain experience with counseling vaccine-hesitant patients. We aim to explore this question through the inclusion of an interaction between period/time and intervention effect in Model 4. Additionally, the intraclass correlation coefficients (ICC) will be estimated and reported, so this information will be available for power analyses for future investigations using similar designs and outcomes. In order to reduce potential bias, during the virtual facilitation period, pharmacists will be instructed to approach patients that they did not approach during the standard facilitation period, which is feasible given the large number of unvaccinated individuals in the communities in which RURAL-CP pharmacies are located.

5.3 Power Analyses

For the primary outcome of fidelity, captured at the pharmacy level, we wish to compare the fidelity scores under standard implementation versus fidelity scores under virtual facilitation. We expect each pharmacy to have approximately 4 fidelity assessments per time period (i.e., a period of 8 weeks). A sample of 30 pharmacies in an incomplete stepped-wedge cluster-randomized design with six periods (five steps), and an average of 10 fidelity assessments per pharmacy yields a total sample size of 320 assessments, which achieves over 90% power to detect a difference between means of 0.53 with a standard deviation of 1 (i.e., moderate effect size). The test statistic is based on a two-sided Wald Z-test with ICC = 0.6 and alpha = 0.05. Given that we will have repeated fidelity measures from the same pharmacists over time, we have specified a conservative ICC (which in a stepped wedge design does not impact power calculations significantly).

For the secondary outcome of effectiveness, we expect each pharmacy to identify approximately 10 vaccine-hesitant patients during each time period (i.e., a period of 8 weeks). A sample of 30 pharmacies in an incomplete stepped-wedge cluster-randomized design with six periods (five steps) and an average of 27 patients per pharmacy yields a total sample size of 800 patients, which achieves over 90% power to detect a difference between effectiveness proportions of 10%. The proportion of vaccine-hesitant patients accepting the vaccine during the virtual facilitation approach is assumed to be 15% compared to 5% under the standard implementation period. These estimates are based on a review of reported changes in vaccine acceptance for evidence-based vaccine hesitancy interventions[40]. The test statistic is based on a two-sided Wald Z-test with ICC = 0.05 and alpha = 0.05. We note that the actual sample size should exceed 800 patients since we expect pharmacies will continue to identify vaccine-hesitant individuals during the follow-up periods.

5.4 Qualitative Data Analysis

We will use rigorous procedures[41] for the analysis of qualitative interview data. Interviews will be transcribed by a professional transcriptionist, who will remove identifying information, and be

imported into MAXQDA, a qualitative data analysis program. The trial team will review several transcripts and meet to discuss the overarching themes related to the CFIR framework (e.g., "not enough time" coded as an "inner context barrier"). These themes will then be incorporated into a codebook with definitions and example quotes to enable structured coding[42,43]. Using rigorous analysis techniques[44], two researchers will use the codebook to independently code each interview and meet to resolve discrepancies. Inter-coder reliability will be calculated. Additionally, we will add specific attributes (e.g., number of scripts filled per day, pharmacy level of rurality) to each transcript, allowing us to examine whether fidelity and effectiveness vary by attribute. Because these interview guides and the quantitative data are both mapped to CFIR constructs, we will be able to conduct concurrent triangulation (comparing results from both data sources on the same questions) as well as elaboration analyses (using the qualitative data to provide depth of understanding to the quantitative findings)[45,46].

6 STUDY INTERVENTION

6.1 Vaccine Hesitancy Counseling Intervention (ASORT)

The vaccine hesitancy counseling intervention, known as "ASORT", will ask pharmacists to identify and engage in COVID-19 vaccine hesitancy counseling with one to two vaccine-hesitant individuals weekly. As noted earlier, we have refined an evidence-based vaccine hesitancy counseling intervention with extensive feedback from rural pharmacists. These refinements resulted in a 5-step counseling process (ASORT; see Table 2) as well as an online resource that provides example verbiage for over 25 vaccine concerns that have been expressed in rural communities. The vaccine hesitancy verbiage is updated periodically with input from our rural patient (four rural patients; two African American, two with Republican party affiliation) advisory board.

6.2 Standard Implementation Approach

The standard approach will train and prepare pharmacists to implement ASORT and provide discrete implementation support tools to support intervention fidelity. Specifically, a trial website will include numerous tools, including example vaccine hesitancy verbiage, sample workflows, marketing materials, and patient pamphlets. The standard approach also includes an online training module developed by the trial team that incorporates similar instructional design principles that have been used previously to develop pharmacist communication-focused modules[47,48]. Finally, just prior to the start time of each block of pharmacies, participants will attend a live webinar or watch a pre-recording with continuing education (CE) credit that includes interactive training on the intervention, updated vaccination recommendations, vaccine storage and delivery, and documentation.

6.3 Virtual Facilitation Approach

The virtual facilitation approach will provide expert guidance from trained facilitators regarding intervention content and implementation processes. The facilitators will perform the following evidence-supported functions[49–53]: engaging stakeholders; building relationships; identifying and training a local facilitator/champion; monitoring progress; providing feedback on progress; identifying implementation barriers; problem-solving; re-training and coaching; and reinforcing change. Facilitators will attend a 16-hour virtually-delivered training in implementation facilitation provided by the Implementation Facilitation Learning Hub, a training center supported by the U.S. Department of

Veterans Affairs (VA) Quality Enhancement Research Initiative (QUERI). The training teaches principles and techniques contained in Dollar et al.'s manual Using Implementation Facilitation to Improve Healthcare (Version 3[52]), which was developed by the VA Behavioral Health QUERI, a research center devoted to supporting the implementation of behavioral health interventions with the VA. The training is highly interactive[54], involving significant practice and role play. Training topics include knowledge, skills, core competencies of facilitators; facilitation roles and activities (e.g., assessing the site, engaging stakeholders, problem identification and resolution); phases of implementation; delivering facilitation virtually; and evaluating facilitation. After the training, the trial co-principal investigator will provide ongoing coaching and supervision to the trial facilitators.

7. SAFETY MANAGEMENT

7.1 Risks related to qualitative interviews

The risks associated with this study for pharmacy staff participating in interviews are primarily breach of confidentiality and distress from answering questions regarding professional practices. Participants might disclose to the interviewer information that could possibly have a negative effect on their pharmacies if it were to become public. However, as described in Section 8 below, all interviews will be kept confidential and transcripts will be de-identified. Written transcripts will not contain names of participants. To minimize distress, during the informed consent process and at the beginning of each interview, we will review the data security procedures used by the study to ensure confidentiality and data safety.

7.2 Risks associated with surveys

The risks associated with pharmacy personnel completing the Feasibility, Acceptability, and Appropriateness surveys are primarily breach of confidentiality. A breach of confidentiality may mean that the information disclosed on the survey (e.g., staff member's ratings of a study intervention as not appropriate for their setting) could lead to discrimination or could possibly have a negative effect on their pharmacies if it were to become public. To prevent this, the surveys are completed on Qualtrics and stored on a secure server at UNC. The data are not viewable by anyone outside the study team once they are completed on Qualtrics (but could be viewed during the completion of the survey if the tablet/computer is left open). All survey data will be kept completely confidential.

7.3 Risks associated with fidelity observations

The risks for participating in the fidelity observations are minimal for pharmacists. Observation guide information will not be shared outside the study team, and therefore, do not pose employment risks for the pharmacist. Pharmacists will receive a study information sheet so they can make an informed decision about whether to participate. Since standardized patients will be used, there is no risk to customers of the pharmacies. The recording is made within the secure Express Dictate mobile app and encrypted recordings are only sent to study personnel, who need the encryption key and Express Dictate desktop software to open. Once the virtual coach has completed the observation guide, the recording will be permanently deleted.

8. DATA COLLECTION AND MANAGEMENT

For pharmacy staff who complete surveys directly in Qualtrics, there will be no need for study staff to enter survey data. Pharmacy staff who complete the paper survey will email a picture or scanned copy to the project manager, who will manually enter the data into Qualtrics and then delete the email. The fidelity observation guide data will be manually entered by study staff into a secure Qualtrics database. For qualitative interviews, all transcripts will be de-identified prior to analysis. The study statistician will perform all analyses using de-identified datasets.

8.1 Monitoring Plan

The study PIs will review interview and survey data as well as fidelity data on a quarterly basis for safety issues. In addition, the entire study team will meet monthly to discuss the study's progression and any potential safety or data concerns.

Potential and reportable events will primarily be breaches of confidentiality. Because the primary outcome is fidelity to the counseling intervention, we do not anticipate serious adverse events related to the study. In the case that an adverse event related to fidelity occurs, the PI will report the adverse event to the IRB and NIH in a timely fashion. In the event that the IRB takes an action that affects the day-to-day operations of the study, the PI will report those actions to the appropriate NIH Project Officer in writing.

If an individual subject decides that they no longer want to participate or is not participating in the data collection activities and has not corresponded with study staff over a 3-month period, they will be withdrawn from the study. There are no criteria that will be used to stop the entire study prematurely.

8.2 Confidentiality of the data

A secure, online survey data collection (Qualtrics) will be used to collect participant survey data. For interviews, participants will be informed that they have the right to refuse audio recording; in such cases the interviewer will take notes. For recorded interviews, the interviewer (who will be UAMS affiliated) will upload each digital recording to a password-protected file on a secure server at UAMS. Audio files will be transcribed by a professional transcriptionist who is employed by UAMS. Audio files will be maintained on the secure UAMS Server until transcription is complete and transcripts are checked for accuracy, at which time they will be destroyed. Recordings for fidelity observations will be made using the secure mobile app Express Dictate, will be encrypted, and will be maintained in secure, password-protected software or on the UNC server until observation guides are completed; then, the recordings will be permanently deleted. Completed survey data will be maintained in the secure Qualtrics system at UNC. Transcripts will be analyzed with a qualitative software package, and the findings generated with this program will be kept in the study folder on the secure server. To further protect confidentiality, we will request that no participant be referred to by name or in any way that would allow a person to be identified during the interview. Should this occur inadvertently, the name would be redacted from the transcript.

De-identified data on rates of delivering vaccine hesitancy counseling and the number of hesitant individuals who received a vaccine will be sent to and used by the study team for analysis. All pharmacy participants are trained in HIPAA compliance by nature of their employment and will not introduce additional risk beyond the normal risk associated with clinician handling of personal health information. Data from pharmacies utilized to calculate quantitative implementation outcomes and effectiveness will be stored in secure, password protected file on a UNC Server. All data on fidelity and effectiveness will

be recorded in aggregate and no identifying or personal health information of customers will be collected.

9. CONSENT PROCESS

Informed consent documents for this study include a specific statement that information from the trial will be posted on ClinicalTrials.gov. The study PIs and project manager will meet with interested individuals for approximately 30 minutes over videoconference to verbally inform them of the details of the study as described in the study information sheet provided to them via email prior to the meeting. The study information sheet includes all aspects of a written informed consent form, including consent information, purpose of the study, length of participation, what is being asked of participants, risks, and benefits. Prospective participants will have the opportunity to ask questions about the study to the study team during the meeting and will be informed of who to contact if additional questions come up at a later time. Once the PIs and project manager have reviewed the entire study information sheet and answered all questions, they will obtain verbal consent from each participant. Individuals who provide verbal consent will be officially enrolled.

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APPENDIX

Figure 1: Stepped wedge study design

Block	Fall 1 2023 Oct-Nov (8 weeks)	Fall 1 2023 Dec-Jan (8 weeks)	Fall 1 2023 Feb-March (8 weeks)	Fall 2 2024 Aug-Sept (8 weeks)	Fall 2 2024 Oct-Nov (8 weeks)	Fall 2 2024 Dec-Jan (8 weeks)
1 (5 pharms)	Standard	Facilitation	Follow-up			
2 (5 pharms)	Standard	Standard	Facilitation	Follow-up		
3 (5 pharms)	Standard	Facilitation	Facilitation	Follow-up		
4 (5 pharms)				Standard	Facilitation	Follow-up
5 (5 pharms)				Standard	Standard	Facilitation
6 (5 pharms)				Standard	Facilitation	Facilitation

Table 1: Outcome measure descriptions and data collection procedures

Measure	Description	Quantitative	Qualitative†
Primary Outcome			
Fidelity	Degree to which the vaccine hesitancy counseling intervention was delivered as intended	Fidelity Checklist that assesses adherence and competence to vaccine hesitancy counseling intervention. Each pharmacist assessed twice per month.	Interviews with pharmacy personnel
Secondary Outcome			
Effectiveness	The proportion of vaccine hesitant individuals who vaccinate after receiving hesitancy counseling	Monthly report completed by pharmacy designee using web-based reporting system	Interviews with pharmacy personnel
Other Measures			
Acceptability	Stakeholder perceptions regarding satisfaction with and appeal of the vaccine hesitancy intervention and implementation approaches	4-item measure completed by pharmacy personnel at end of standard & virtual facilitation approach	Semi-structured interviews with pharmacy personnel
Uptake	How often vaccine hesitancy counseling was offered to hesitant individuals	Monthly report completed by pharmacy designee using web-based reporting system	
Appropriateness	Stakeholder perceptions regarding fit and suitability of the vaccine hesitancy intervention and implementation approaches	4-item measure completed by pharmacy personnel at end of standard & virtual facilitation approach	
Feasibility	Stakeholder perceptions regarding ease and "do-ability" of the vaccine hesitancy intervention and implementation approaches	4-item measure completed by pharmacy personnel at end of standard & virtual facilitation approach	
Organizational Structure and Context	Key structural aspects of pharmacy (e.g., size/staffing) and organizational capacity for change	Structure survey completed by one pharmacist before randomization; context survey completed by ≥ 5 pharmacy personnel	N/A
Sustainment	Continued measurement of fidelity, effectiveness, and uptake during the "follow-up" periods	See above entries for fidelity, effectiveness, and uptake	
Cost	Costs associated with deployment of each implementation approach.	Log of time and activities completed monthly by facilitator	

† qualitative data will be collected after the end of the virtual facilitation period with 1 high performing and 1 low performing pharmacies per block

Table 2: Selected content from the 5-step vaccine hesitancy counseling process (ASORT)

Step	Recommendations & Example Verbiage
Ask if they would like to receive a COVID vaccination	• People are more open to talking about the COVID-19 vaccine if you ask while you're doing other activities, like giving a flu shot or engaging in medication therapy management. *"While I'm giving your flu shot, I just thought I'd ask if you've gotten your COVID vaccine yet."* • Offer praise to people who are up-to-date on their vaccination
Solicit their main vaccine concern	• People often have multiple concerns about the vaccine, but one concern will likely loom larger than the others, so this is the concern you'll want to focus on first. *"Can you tell me more about that?"*
Offer to address their concerns	• People have different levels of readiness to discuss the vaccine, so it's important to ask for permission to share more information about their concerns. • Start by validating their concerns so they know that you're not judging them. *"I know several other people who have had that same concern and I've shared some information with them that they've found useful. I'd be happy to share that same information with you if you want."* • Some people won't be ready for more information and that's okay. Just let them know that you understand. *"Ok. No problem. Know that I'm here if you do ever want to talk."* • Address their concerns • For individuals who aren't ready, skip to the last step.
Recommend the vaccine	• Share your personal experience with the vaccine and that you trust it before you recommend it. This can help build their trust in the vaccine. • After sharing your personal experience, then recommend the vaccine. *"I wouldn't recommend the vaccine if I didn't think it was safe. I received it and I trust it. That's why I recommend that you get the vaccine - because I care about you and want you to keep you safe."* • You can also tie your recommendation to any factors that may put them or their family members at higher risk for severe COVID complications. • If they are still unsure or refuse, then move to Step 5.
Try again later if they refuse or are unsure	• As we've seen throughout the pandemic, many people who say they will never get the vaccine have since been vaccinated. So don't be discouraged if they refuse. React in a positive way and let them know you'll check in with them again. *"Thanks for considering it. I'll check in with you again if I hear any new information about your concern."* • Since people can and do change their minds, it's important to try again during one of their next visits to the pharmacy. • For regular customers, keep a list of people to follow up with or make a note in the pharmacy record to follow up.